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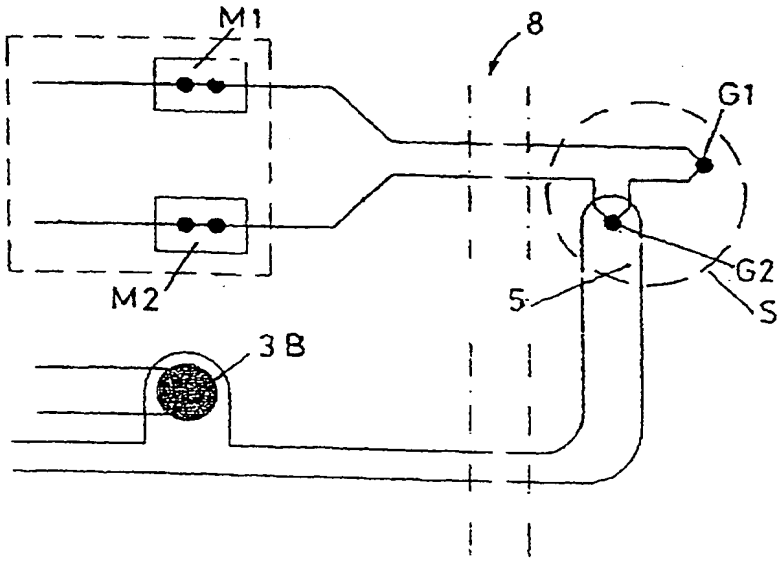
Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv)) for US only*

[Continued on next page]

(54) Title: APPARATUS FOR PHYSIOTHERAPIC HYPERTHERMIA TREATMENTS



(57) Abstract: Apparatus for physiotherapic hyperthermia treatments comprising: - one endogenous heat source (1) and one exogenous heat source (2), both sources being under controlled temperatures (Tes and Ts); - means to apply heat to an area (S) of the patient's skin that corresponds to the part of the body to be treated; the heat is applied as a result of control input signals; - means to control the temperature (Tt) of the body part to be treated, which is attained in consequence of the application of heat. Temperature control shall be achieved as a function of at least temperature (Ts) of the skin area (S) and of Tes. The temperature control means indicated include the means for direct measurement of the temperature difference Δ(Tes-Ts) between the temperature of the exogenous heat source and the temperature of the skin area (S).

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Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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APPARATUS FOR PHYSIOTHERAPIC HYPERTHERMIA TREATMENTS

Area of Applicability of The Invention

The invention belongs to the sector that includes the apparatuses for physiotherapic treatments through hyperthermia.

As known, at least since the Seventies, the word "hyperthermia" has been more and more tightly associated to the concepts of great effectiveness of deep-reaching heat and of high accuracy in the determination of the temperature and distribution of such a heat.

As a result, an apparatus designed to induce hyperthermia for therapeutic purposes shall include, among its other functions and devices, a system for the measurement of temperature which is extremely accurate and more or less complex, depending on the specific objective of the intended therapy.

Nowadays, hyperthermia can be defined as "the heat therapy able to treat the involved tissues in the small temperature interval in which heat has a healing effect that helps to achieve physical rehabilitation".

It is also known that the mentioned interval is the one between the limit temperatures of 37 and 45.5°C, and that, normally, a much smaller interval is used that is specific for the area to be treated and for the involved pathology.

In general, the conventional heat therapies applicable are far from meeting the requirement mentioned above – the treatment temperature varies over a wide range of almost random values and, therefore, the apparatuses used for them cannot be included among those specific for hyperthermia.

State of the art

Currently, an already well tested and validated method to obtain an effective heating consists of the concurrent local application of endogenous heat having a

high penetration depth and exogenous heat having highly stabilizing power on the surface of the part to be treated. The endogenous heat is generated by electromagnetic waves at a frequency of 434 MHz, the exogenous heat through a thermo-regulated fluid that is circulated in a thin-walled bag that is put in contact with the area to be treated. Control of the heat sources is obtained through temperature measurements made by a suitable number of sensors installed in the correct positions, which are sufficiently independent to provide adequate control of each of the two heat sources. Also, the sensors must be of the non-invasive type, because invasive type sensors are unacceptable as far as physiotherapy is concerned.

The two temperature measurements that meet the specified requirements are those related to the temperature of the interface between the skin and the bag that contains the thermo-regulated fluid (bolus) - at the point of maximum electromagnetic radiation - and the temperature of the fluid. It can be demonstrated, both theoretically and experimentally, that they are sufficiently independent to permit control of the two sources, provided that their values are known with sufficient accuracy.

An apparatus of this type is described in Italian patent IT01247029.

Yet, the already known apparatuses have some limitations as to the accuracy of the measurement of the temperature of the skin at the bolus bag interface which are linked to the control of the endogenous source. Such limitations have an impact on the control of the treatment, and, consequently, on the quality of the therapy.

Purpose of the invention

The first purpose of this invention is, therefore, to achieve better control -both in

terms of accuracy and reliability - of the temperature that is attained in the deeper layers of tissue during the application of physiotherapic hyperthermia treatment.

The second purpose is to obtain such an accuracy at a limited cost so as to achieve a widespread adoption of physioterapic hyperthermia made by use of dual heat source apparatuses – an endogenous source to heat the deep-laying tissues and an exogenous source for surface temperature control.

Summary of the invention

To achieve the specified purposes, an apparatus for physiotherapic hyperthermia has been realized, according to the main claim described herein.

Additional advantages are obtained through the solutions subject of the secondary claims.

List of drawings

The mentioned and other additional advantages will be more clearly understood by any technician specialized in the field basing on the following description and the attached drawings provided as examples. The drawings shall not be considered as binding.

- Fig. 1 shows the schematic diagram of an apparatus intended for physiotherapic hyperthermia treatment;

- Fig.2 shows a schematics of the conventional temperature measuring system of an apparatus as the one shown in Fig. 1;

- Fig.3 shows a schematics of the temperature measuring system as the one installed in an apparatus as invented.

Detailed description

Ref. Fig. 1.

Any conventional physiotherapic hyperthermia apparatus includes an endogenous

heat source (1), and an exogenous heat source (2). Both heat sources are managed through an electronic controller (4) that uses, as a feedback, the temperature measurements sent by a thermometer made up of electronic circuits (3A), that you can see in Fig. 1, and a sensor (3B) that you can see in Fig. 2. Another thermometer still made of electronic circuits (6A) that you can see in Fig.1 and a sensor (6B), also shown in Fig. 2, complete the system.

As an example, source (2) consists of a thermo-regulated fluid module the temperature of which is controlled by controller (4) through the thermometer (3A, 3B). The fluid is circulated within a bag (5) that is placed on an area (S) of the patient's body. Source number 1 consists of an electromagnetic wave generator that generates electromagnetic waves at the approximate frequency of 434 MHz which go through an applicator (9) and reach area (S) of the patient's body. In the described case, the applicator is a "Ridged Horn" antenna with the bag (5) in which the thermo-regulated fluid transparent to the working frequency circulates, integrated.

A temperature sensor (6B) is located between the applicator (9) and the area to be treated. The temperature sensor (6B) which is shown in detail in figure 2, gives the "skin" temperature. In the case of figure 2, sensor 6B is a normal thermocouple.

By referring to figure 3, it can be observed that, in this invention, and different from the conventional apparatuses (Fig. 2) which use separate temperature measuring channels for each measurement point, the apparatus is fitted with a sensor (8) which is specialized for the accurate and direct measurement of the difference between the temperature of the fluid of the exogenous source and the skin temperature measured at the interface between the bag (5) and the area to be treated (S).

Still by referring to figure 3, a temperature sensor (8) of the type fitted to the invented apparatus includes two type T (copper – constantan) thermocouples having junctions G1 and G2, the first of which is placed at the interface between the bag (5) and the patient's body, and the second is in thermal contact with the thermo-regulated fluid of the exogenous source (2).

At terminals M1 and M2 it is thus possible to measure a voltage proportional to the difference between the temperatures sensed by junctions G1 and G2.

An advantage given by the type of used thermocouples is that two copper wires reach terminals M1 and M2. In this way extraneous thermo-electrical phoenomena occurring at the two terminals are negligible.

The fluid temperature is measured by use of an absolute sensor (3B), that also permits the results of the differential measurements to be tranformed in absolute values whenever required.

From the above, the advantages offered by the selection of the absolute fluid temperature as the first temperature measurement become quite evident. This temperature is measured by the same sensor that provides its thermo-regulation. The difference between the temperature of the bag and bag-skin interface is obtained by placing a G1 thermocouple at the interface, and a G2 thermocouple (reference junction) in tight thermal contact with the fluid.

In a preferred design, reference junction G2 is installed where the fluid enters the bag (5). In this case, if a relatively fast circulation of the fluid is selected, the fluid flowing out of the bag to return to the thermo-regulation module is still nearly (tolerance is approx. 0.1°C) at the same temperature as when it flowed into the bag. This means that the measurement point is the ideal one for this purpose because it is the closest possible to the actual temperature of the fluid contained in

the bag.

The invention also features a method for temperature control in applications related to physioterapic hyperthermia, which is based preferably on the devices that were described above.

The following phases apply:

- determination of the temperature (T1) that must be attained in the treatment area;
- application of heat in the skin area (S) that corresponds to the body part to treat. This is achieved by use of an endogenous, radio-frequency heat source;
- heating of the skin area (S) of the body part to be treated by use of an exogenous controlled and constant temperature (Tes) heat source;
- direct measurement of temperature difference Δ(Tes-Ts) between Tes and skin temperature Ts in area (S).
- calculation of temperature Tt of the area to be treated, as a function of Δ(Tes-Ts) and Tes;
- adjustment of electromagnetic energy emission from the endogenous source as a function of the measured and estimated temperatures.

Example of application

A comparison between the operation of the apparatus as invented and that of a conventional type apparatus is detailed hereafter. The following has to be taken into account:

a) Errors affecting the measurements of the fluid and of the skin temperature in a way that the measurement of the difference between the two temperatures is correct, are transferred approximately unchanged on the estimated maximum internal temperature. As an example, a 1°C error both

on the fluid and on the skin temperature measurements (errors must have the same sign) will result in an error of approximately 1°C affecting the estimated maximum internal temperature;

b) An error affecting the measurement of the difference between the fluid temperature and the skin temperature is transferred, approximately doubled, on the estimated maximum internal temperature. This means, for instance, that a 1°C error on the measurement of the difference between the fluid temperature and the skin temperature will result in an error of approximately 2°C on the estimated maximum internal temperature.

Let's assume now (case "a") that the error concerning the fluid temperature is negligible - this is possible if the temperature measuring circuit and the hydraulic circuit are correctly designed and built - and the error concerning the temperature measured by the skin thermocouple G1 is +0.5 or -0.5°C.

(Note that the above mentioned error is the typical tolerance applicable to most of the modules that are available commercially and described in the applicable literature, and the reasons for this are two: First it is difficult to obtain the necessary thermal coupling between the reference junction and the absolute correction sensor on a printed circuit board, and, second, higher performance levels are not usually required).

This means that, if you select, for instance, a $\Delta T = 0$ the control circuit (4) may read $\Delta T = +0.5°C$ or $\Delta T = -0.5°C$, corresponding to very different electromagnetic energy emission levels (the difference may range from 0 to a few tens of Watt). In the area of maximum temperature inside the patient's body, where the error is approximately twice as much, there can be an error of $\pm$ 1°C with respect to the desired value. Since a further 1°C error can be expected due to factors that cannot

be controlled and are independent of the apparatus, it may happen that a treatment suitable for muscle tissues is carried out instead of the intended treatment optimized for connective tissues, or vice versa. This, obviously, makes the patient's recovery time longer.

Conversely, (case "b") if ΔT is measured directly by use of the apparatus according to the invention, the error concerning ΔT will be extremely small, e.g. not greater than 0.15°C, all other conditions remaining unchanged. Therefore, the treatments will be much more accurate, and it will be possible to carefully select the types of tissues to treat. Advantageously, the apparatus operates in a temperature interval optimized for physiotherapic hyperthermia, therefore a higher accuracy is obtained as far as the estimated internal temperature distribution, and, in consequence, the control of the hyperthermia treatment are concerned, at the same costs and with equivalent means.

It is to be highlighted that the mentioned feature is even more important when it is necessary to heat the tissues up only to a very limited extent, that is, when scarcely blood supplied tissues are to be treated. This because, in such cases, the ΔT required and to be controlled is very small, and, consequently, an error in the measurements has a greater negative impact on the effectiveness of the treatment.

The peculiar effectiveness, ease of application and use of the apparatus that is the subject of the invention are further evident in the above cases.

From what described above, it is clear that, given that it is important to keep the temperature measurement errors as small as possible, it is essential to take a particularly good care of the accuracy of the measurement of the difference between the two temperatures, rather than of the accuracy of each individual

temperature measurement. This is the innovative feature of the invention covered herein.

The invention has been described with reference to preferred implementation solutions, but it is to be understood that any technician expert in the field will be able to embody equivalent modifications without the rights bestowed according to the claimed patent being voided.

CLAIMS

1. Apparatus for physiotherapic hyperthermia treatments, comprising:

- an endogenous heat source (1) and an exogenous heat source (2); both sources being under controlled temperatures (Tes and Ts);
- means to apply such a heat under controlled input to an area (S) of the patient's skin corresponding to a part of the patient's body to be treated;
- means to control the temperature (Tt) of the body part to be treated, which is attained as a result of the application of the mentioned heat, as a function of at least the temperature (Ts) of such an area (S) and of Tes,

characterized in that said control means include means for the direct measurement of the difference Δ(Tes-Ts) between the temperature of the exogenous source and the temperature of the skin in the area (S) to be treated.

2. Apparatus according to claim 1, wherein the said means for the measurement of Δ(Tes-Ts) consist of a single temperature measuring module (8) comprising two electrically connected thermocouples (G1, G2), the first sensing the temperature in area (S), and the second in thermal contact with the exogenous temperature-controlled heat source (2).

3. Apparatus according to claim 2, where:

- the source (2) consists of a module containing thermo-regulated fluid that is circulated through a bag-type applicator (5) designed to be placed on the area to be treated (S);
- the source (1) consists of an approx. frequency of 434 MHz electromagnetic wave generator that emits waves that reach area (S) from the applicator (9) and the bag (5);
- temperature Tes is measured by an absolute sensor (3);

- said means to control the temperature (Tt) include a controller (4), that receives a value (Tes) from sensor (3), a value Δ(Tes-Ts) from module (8), and a unit that computes Tt as a function of Δ(Tes-Ts) and Tes, as well as means to control the emission of electromagnetic energy by the endogenous source (1) as a function of the measured and estimated temperature values.

4. Apparatus according to claim 3, characterized in that the reference junction (G2) is installed in proximity of the point where the fluid enters the bag (5).

5. Method for temperature control in case of physiotherapic hyperthermia treatments comprising the following steps:

- determination of the correct temperature (Tt) to be obtained in the treatment area;
- application of heat in the skin area (S) corresponding to the body part to be treated by use of a radio-frequency endogenous source;
- application of heat in the skin area (S) by use of an exogenous source under constant, controlled temperature (Tes);

characterized in that it comprises also the following steps:

- direct measurement of the temperature difference Δ(Tes-Ts) between (Tes) and the skin temperature in area (S), (Ts).
- calculation of the temperature (Tt) attained in the area to be treated by application of heat, as a function of Δ(Tes-Ts) and (Tes);
- regulation of the electromagnetic energy emitted by the endogenous source as a function of the measured and estimated temperature values.

6. Method according to claim 5, wherein said endogenous heat source operates at a frequency included in the ISM (Industrial, Scientific, Medical) interval the central value of which is 433. 920 MHz.

7. Method according to claim 5, wherein said measurement of Δ(Tes-Ts) is performed through a temperature measuring module including thermocouples.

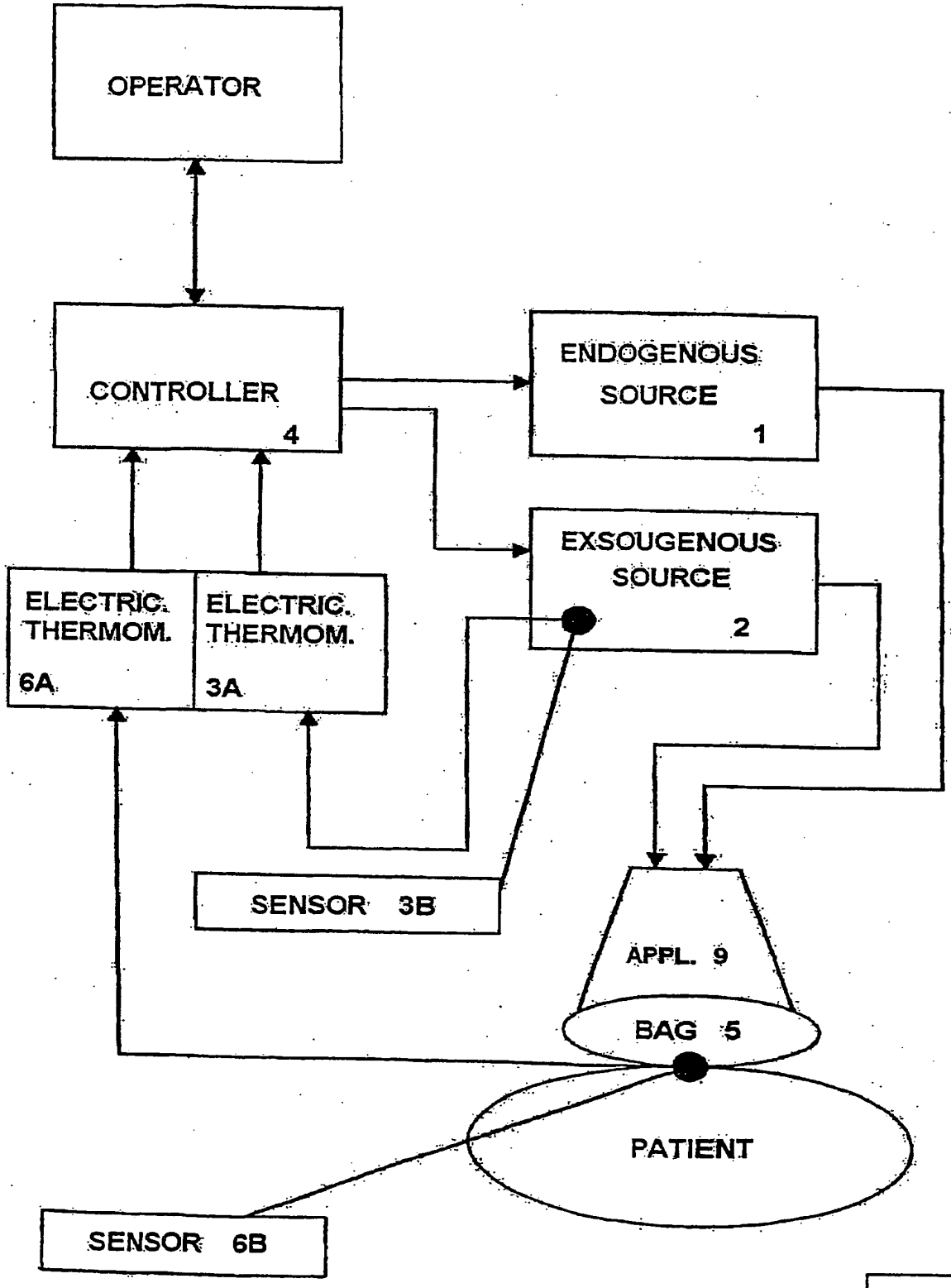
8. Method according to claim 5, wherein said temperature (Tes) is comprised in the range from 20 C° to 50 C°.

9. Method according to claim 5, wherein said temperature (T1) is comprised in the range from 37 C° to 46 C°.

10. Sensor for the measurement of the induced temperature in physiotherapic hyperthermia treatments comprising two heat sources – one endogenous and the other exogenous

characterized in that such sensor comprises means for directly measuring the temperature difference Δ(Tes-Ts) between the temperature of the exogenous heat source (Tes) and the skin temperature (Ts) obtained in area (S) as a result of the application of both exogenous and endogenous heat.

11. Sensor according to claim 10, wherein said means comprise two thermocouples (G1, G2) in electrical contact, the first being in thermal contact with area (S), the second being in thermal contact with the exogenous heat source (2) under controlled temperature (Tes).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SENSOR 6B

FIG. 1

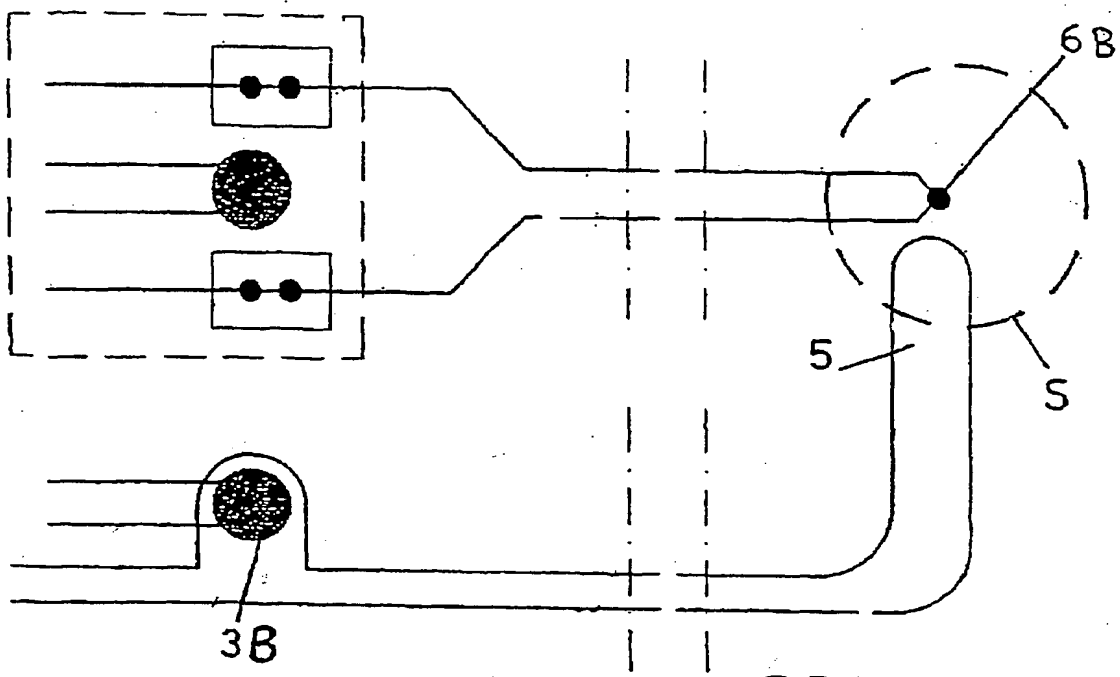

FIG.2

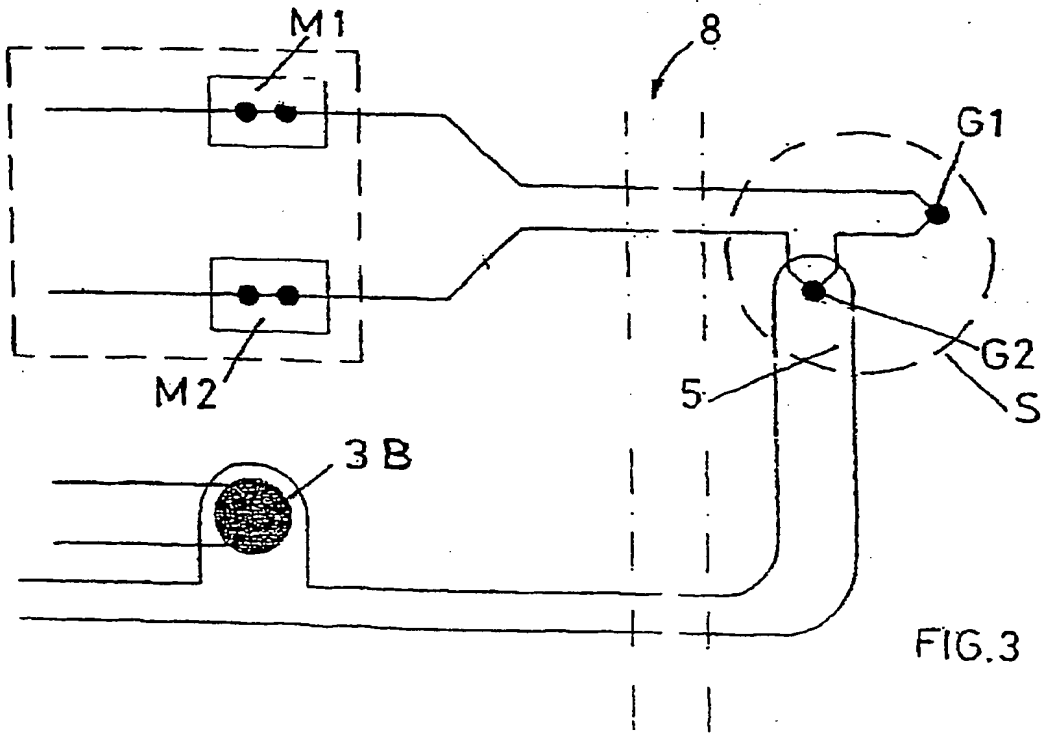

FIG.3

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/EP 02/07118

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N5/02 A61F7/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 519 415 A (SMA SEGNALAMENTO MARITTIMO ED) 23 December 1992 (1992-12-23) column 3, line 12 - line 45	1-4,10, 11
Y	US 6 162 184 A (FLEISCHMAN SIDNEY D ET AL) 19 December 2000 (2000-12-19) column 8, line 58 -column 9, line 41; figure 12A	1-4,10, 11
A	WO 88 03823 A (BSD MEDICAL CORP) 2 June 1988 (1988-06-02) page 18, paragraph 4 -page 19, paragraph 1	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 November 2002	12/11/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Mayer, E

INTERNATIONAL SEARCH REPORT

national application No.
PCT/EP 02/07118

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 5-9
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

ormation on patent family members

Inte[illegible]nal Application No
PCT/EP 02/07118

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